

## **REMARKS/ARGUMENTS**

By the present amendment, applicants have cancelled Claims 5-11 since such claims are drawn to a non-elected invention. In addition, applicants have amended Claims 1 and 19, and added new Claims 20 and 21 to include a percent purity for the crystalline salt. Support is found in applicants' specification, as originally filed, on page 2, lines 16-18. Therefore, the claims remaining for consideration by the Examiner are Claims 1-4 and 12-21.

### **I. Restriction Under 35 U.S.C. § 121**

The Examiner required restriction under 35 U.S.C. § 121 to the subject matter of:

Group I: Claims 1-4, 12-19, drawn to salts, classified in class 540, subclass 222.

Group II: Claims 5-11 drawn to Process, classified in class 540, subclass 222.

Applicants affirm their election to prosecute the invention of Group I, Claims 1-4, and 12-19.

### **II. Rejection of Claims 1-4 and 14 under 35 U.S.C. § 102 (b)**

The Examiner has rejected Claims 1-4 and 14 under 35 U.S.C. § 102 (b) as being anticipated by Lin et al..

Lin teaches a synthesis for preparing the hydrochloric acid salt of 7-[2-(2-aminothiazol-4-yl)-2-(methylcarbonyloxyimino)acetamido-3-vinyl-cephem-4-carboxylic acid (Compound 4).

In contrast, applicants' amended Claim 1 contains the limitation that the crystalline salt has a purity of at least 90% by weight as determined by the percent HPLC area. Thus, the rejection under 35 U.S.C. § 102 (b) is improper.

### **III. Rejection of Claims 1-4 and 14 under 35 U.S.C. § 103 (a)**

The Examiner has rejected Claims 1-4 and 14 under 35 U.S.C. § 103 (a) as being obvious over Lin et al.

The Lin reference does not teach or suggest a salt of 7-[2-(2-aminothiazol-4-yl)-2-(methylcarbonyloxyimino)acetamido-3-vinyl-cephem-4-carboxylic acid having a purity of at least 90% by weight as determined by the percent HPLC area. It is clear from the synthesis of Compound 4 of Lin, which is a hydrochloride salt, that the Lin compound is less pure than applicants' claimed compound. This is evident from the synthesis set forth in Lin which employs

a benzhydryl group for the deprotection of the  $\beta$ -lactam in the in the synthesis of Compound 3 to Compound 4. In addition, to remove the benzhydryl protecting group, Lin uses  $\text{BF}_3/\text{EtOEt}$ .

It is noted that applicants employ only one deprotecting step using an acetyl protecting group in the synthesis of the compound according to Claim 1 to provide a compound having a purity of at least 90% by weight as determined by the percent HPLC area. In contrast, Lin employs two deprotecting steps which involves more organic compounds than applicants. Thus, one skilled in the art would expect the compound of Lin to be much less pure than applicants' compound as claimed.

The Examiner has rejected Claims 1-4 and 14 under 35 U.S.C. § 103 (a) as being obvious over JP 59-194186.

JP 59-194186 teaches pivaloyloxy esters. It is clear to one skilled in the art that such pivaloyloxy esters are completely different than the methyl esters claimed by applicants for a number of reasons. First, the pivaloyloxy esters are sterically different than applicants' methyl esters. Second, the reactivity of the pivaloyloxy esters is completely different than the reactivity of applicants' methyl esters. Thus, JP 59-194186 does not render applicants' claims obvious.

#### **IV. Rejection of Claims 3 and 19 under 35 U.S.C. § 112**

The Examiner has rejected Claims 3 and 19 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner states the following:

1. In Claim 3, the next to last X choice should have the minus sign raised, not lowered.
2. In Claim 3, the choice of  $\text{Y}=\text{P}$  is unclear.
3. In Claim 19, "substantially pure" is indefinite.

In response, applicants have amended Claim 3 to raise the minus sign. In addition, applicants have amended Claim 3 to exclude  $\text{Y}=\text{P}$ .

#### **V. Claim Objections**

The Examiner has objected to Claim 12 as being in error for containing the term, "optionally".

In response, applicants have amended Claim 12 to remove the term, "optionally in crystalline form".

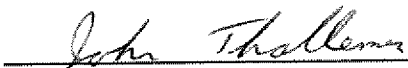
The Examiner has objected to Claim 14 as being improperly dependant on Claim 12.

In response, applicants have amended Claim 12 to include the term, " hydrochloride". Support is found in applicants' specification in Fig. 2 on page 6/14 of applicants' specification, as originally filed.

In view of the foregoing amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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